

K954906

SUMMARY OF SAFETY AND EFFICACY

- A. The submitter's name, address, telephone number, contact person, and date of preparation.

Submitted by Becton Dickinson Vascular Access, 9450 South State Street, Sandy, UT 84070.
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- B. The name of the device including trade or proprietary name if applicable, the common or usual name, and the classification name.

Name: Introducer Catheter
Brand: FIRST PICC™
Common Name: Introducer Catheter
Classification Name: Intravascular Catheter (80 FOZ)

- C. An identification of the predicate or legally marketed device to which substantial equivalence is claimed:

Predicate Device: The Becton Dickinson Vascular Access INSYTE® brand and SPLIT SECOND® brand introducer catheters and the Teleflex, Inc. Percutaneous Introducer Set.

- D. A description of the device that is the subject of the Premarket Notification submission.

The subject catheter is a short term, single use introducer catheter of various gauges and lengths which is designed to split and peel away following use. It is inserted into the vascular system over a needle.

- E. Statement of intended use of the device.

The intended use is to facilitate the placement of other devices such as guidewires, central venous catheters, peripherally inserted central venous catheters, and probes in the vascular system.

- F. A statement of how the technological characteristics compare to those of the predicate or legally marketed device identified in section C above.

The proposed catheter differs from the INSYTE® brand introducer catheter in that it is splittable; however, the intended use is the same. It is similar to the SPLIT SECOND® brand introducer catheter and the Teleflex, Inc. Percutaneous Introducer Set in that both are splittable and both are introducer catheters.